REMARKS

In an Office Action dated October 27, 2008, claims 1, 2, 4 - 9, 11 - 15 and 17 are pending and all claims stand rejected. Claim 2 has been amended to recite compounds only. Support for the amendment to Claim 2 is provided in the specification at page 3 - 6 and Example 1. Claims 1, 2, 4 - 9, 11 - 15 and 17 are currently pending.

Nonstatutory obviousness-type double patenting

Claims 1, 2, 4 - 9, 11 - 15 and 17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 16 of U.S. Patent No. 6,113,920 in view of Rudnic et al. Applicants respectfully disagree. Neither reference discloses the pharmaceutical composition of an immediate release formulation of zidovudine together with a sustained release formulation of lamivudine and zidovudine **for once daily administration**. The compositions of the present invention provide for an immediate release of zidovudine and lamivudine for the initial release period, thereby ensuring safety in administering the drugs followed by a controlled release of zidovudine in the small intestine to maximize absorption in that portion of the gastrointestinal tract, because the colonic absorption of zidovudine is very low (specification at page 5). The recommended oral dose of the marketed product, Combivir® (lamivudine and zidovudine), is one tablet twice daily. Because convenience and compliance are essential in the treatment of HIV disease, if the compositions of the present invention were obvious, then one may have expected a once daily lamivudine/zidovudine product.

Applicants respectfully request withdrawal of the rejection of claims 1, 2, 4 - 9, 11 - 15 and 17 on the ground of nonstatutory obviousness-type double patenting.

35 U.S.C. § 103 (a)

Claims 1, 2, 4 - 9, 11 - 15 and 17 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Rudnic in view of Cameron and further in view of Lui. Claim 1 has been amended to recite the release time of zidovudine. Support for the amendment to Claim 1 may be found in the specification at pages 5 - 6. Applicants respectfully disagree with the claim rejections. The references do not disclose the specific pharmaceutical composition of an immediate release formulation of zidovudine together with a sustained release formulation of lamivudine and zidovudine **for once daily administration.** Lui concerns compositions containing

one medicament, preferably ibuprofen or salts of ibuprofen. The short half-life of zidovudine in the blood and zidovudine's preferential absorption on the upper part of the gastrointestinal tract were thought to preclude once daily dosing (specification at page 3). Indeed, the marketed product is for twice daily administration. Because convenience and compliance are essential in the treatment of HIV disease, if the compositions of the present invention were obvious, then one may have expected to then one may have expected a once daily lamivudine/zidovudine product.

Applicants respectfully request withdrawal of the rejection of claims 1, 2, 4 - 9, 11 - 15 and 17 under 35 U.S.C. § 103 (a).

Applicants request a 3-month extension of time to extend the response period up to and including April 27, 2009. The Commissioner is authorized to charge such fees and any other fees required or credit any overpayment to Deposit Account No. 07-1392.

It is respectfully submitted that the present application is in condition for examination. An early consideration and notice of allowance are earnestly solicited.

Respectfully submitted,

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